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State of California—Health and Human Services Agency  
**California Department of Public Health**



EDMUND G. BROWN JR.  
Governor

May 18, 2012

AFL 12-26

**TO:** All Clinics  
Ambulatory Surgery Centers (ASCs)

**SUBJECT:** Outpatient Settings Adverse Event Reporting Requirements

**AUTHORITY:** Health and Safety Code (HSC) Sections 1248, 1248.15(h), 1279.1 and 1280.4

This letter serves to notify all clinics and ASCs that also meet the definition of an “Outpatient Setting” as specified in HSC Chapter 1.3 (Sections 1248-1248.85) of a new statutory requirement for reporting adverse events.

An “outpatient setting” is defined in HSC Section 1248 as “any facility, clinic, unlicensed clinic, center, office or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia, or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient’s life-preserving protective reflexes.” A clinic or ASC that does not meet this definition (i.e. use general anesthesia) is not subject to these reporting requirements.

Pursuant to HSC 1248.15 (h), effective January 1, 2012, outpatient settings are subject to the reporting requirements of Section 1279.1 and the penalties for failure to report specified in Section 1280.4.

All outpatient settings must now report adverse events to the California Department of Public Health (CDPH), Licensing & Certification Program (L&C), no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel or visitors, not later than 24 hours after the adverse event has been detected. In addition to reporting the incident to CDPH, the clinic/outpatient setting is required to notify the patient or the patient’s representative of the adverse event within the same reporting timeframes.

Outpatient settings are further subject to a one hundred dollars (\$100)-a-day penalty for each day that the facility failed to report an adverse event following the five-day or 24-hour reporting period.

HSC 1279.1 identifies 28 various events that qualify as “adverse events;” see Attachment A for a complete list.

To report a possible adverse event, a licensed clinic/outpatient setting should contact its respective CDPH L&C District Office responsible for its oversight. At this time there is no prescribed format for reporting. Licensed clinics/outpatient settings may submit adverse event reports in the manner of their choosing (by phone, fax, email, or letter). L&C District Office staff will request any additional information necessary to confirm whether or not the circumstances would be considered an adverse event and/or to determine whether further investigation is required.

While not an exhaustive list, the department has identified the following information as beneficial to making such determinations:

- Clinic/Facility name
- Location of facility; Address and City
- Contact person; including name, telephone number and fax number
- Date adverse event occurred or date detected
- Date the adverse event is being reported
- Identification of adverse event category
- A brief description of the event (for events categorized under 1279.1 (b)(7))
- Date patient or party responsible for the patient was notified of the adverse event

It is important to note that outpatient settings that do not report a possible adverse event to CDPH are subject to penalties for the period of time the event remained unreported if it is later determined that the incident should have been reported. Further, this new reporting requirement in no way replaces or alters the reporting requirements for "Unusual Occurrences" as defined in California regulations.

Licensed clinics and ASCs are responsible for following all applicable laws. The California Department of Public Health's failure to expressly notify facilities of statutory or regulatory requirements does not relieve them of their responsibility for following all laws and regulations. All clinics and outpatient settings should refer to the full text of all applicable sections of the Health and Safety Code.

If you have any questions, please contact your respective L&C District Office. For your convenience the list of all District Office addresses and contact information can be found using the following link:

<http://www.cdph.ca.gov/certlic/facilities/Pages/LCDistrictOffices.aspx>

Sincerely,

**Original Signed by Debby Rogers**

Debby Rogers, RN, MS, FAEN  
Deputy Director  
Center for Health Care Quality

## **Attachment A – Adverse Events**

Per California Health & Safety Code, Section 1279.1 (b), "adverse event" includes any of the following:

### **(1) Surgical events, including the following:**

- (A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
- (B) Surgery performed on the wrong patient.
- (C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.
- (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
- (E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

### **(2) Product or device events, including the following:**

- (A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.
- (B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
- (C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

**(3) Patient protection events, including the following:**

- (A) An infant discharged to the wrong person.
- (B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision-making capacity.
- (C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

**(4) Care management events, including the following:**

- (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
- (B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- (C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
- (D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.
- (E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
- (F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
- (G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

**(5) Environmental events, including the following:**

- (A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.
- (B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

- (C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.
- (D) A patient death associated with a fall while being cared for in a health facility.
- (E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

**(6) Criminal events, including the following:**

- (A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- (B) The abduction of a patient of any age.
- (C) The sexual assault on a patient within or on the grounds of a health facility.
- (D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

**(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.**